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EXAMINER  
MAGLIONE, C

33M1/0727

ART UNIT PAPER NUMBER

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3306

DATE MAILED: 07/27/95

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

☐ This application has been examined ☒ Responsive to communication filed on 3/23/95 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s),        days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- ☐ Notice of References Cited by Examiner, PTO-892.
- ☒ Notice of Art Cited by Applicant, PTO-1449.
- ☐ Information on How to Effect Drawing Changes, PTO-1474.
- ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
- ☐ Notice of Informal Patent Application, PTO-152.
- ☐ \_\_\_\_\_

Part II SUMMARY OF ACTION

1. ☒ Claims 1-9 and 13-60 are pending in the application.

Of the above, claims \_\_\_\_\_ are withdrawn from consideration.

2. ☐ Claims \_\_\_\_\_ have been cancelled.

3. ☐ Claims \_\_\_\_\_ are allowed.

4. ☒ Claims 1-9, 13-34 and 37-60 are rejected.

5. ☒ Claims 35 and 36 are objected to.

6. ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed \_\_\_\_\_, has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

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### ***Oath/Declaration***

The oath or declaration is defective. A new oath or declaration in compliance with 37 C.F.R. § 1.67(a) identifying this application by its Serial Number and filing date is required. See M.P.E.P. §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the United States application for patent on which the benefit is claimed under 35 U.S.C. § 120 by specifying the application serial number, filing date and status.

### ***Drawings***

The drawings are objected to under 37 C.F.R. § 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the restraint that holds said puncturing element in a retracted position must be shown or the feature cancelled from the claim. No new matter should be entered.

### ***Specification***

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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The specification is objected to under 35 U.S.C. § 112, first paragraph, as the specification, as originally filed, does not provide support for the invention as is now claimed.

There is no support set forth in the specification for a "restraint" that holds the puncturing element in a retracted position and, when removed, the puncturing element is automatically moved to a puncturing position.

***Claim Rejections - 35 USC § 112***

Claims 1-9 and 13-31 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 7-9, 13-21, 33, 34 and 37-60 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is found to be incomplete because there is set forth no structural communication or relationship between the "restraint" and the "catheter".

There is no antecedent basis for "The invention" of claims 16 and 50.

Claim 33 is found to be confusing because "with the puncturing element" is repeated twice within the claim.

There is no antecedent basis in claim 38 for "said drug" or for the delivery of the drug.

There is no antecedent basis in claims 39 and 40 for "the step of delivering the drug".

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There is no antecedent basis in claim 41 for "the delivery means".

Claim 42 is found to be incomplete because there is set forth no structural relationship or communication between "a movable surface" and the rest of the device.

In claim 43 "an inflatable compartment" is merely inferentially included in the claim and not positively recited. Further, there is no antecedent basis for "said inflatable compartment".

There is no antecedent basis in claims 53-60 for "The method".

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 32-34, 37-39, 41, 42, 44, 45 and 52 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Lemelson.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a

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whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 40 and 53-60 are rejected under 35 U.S.C. § 103 as being unpatentable over Lemelson.

Lemelson discloses the claimed invention except for the specific types of drugs which are to be injected into the tissue through the device. It would have been an obvious matter of design choice to inject the drugs as claimed, since applicant has not disclosed that any one of the claimed drugs solves any stated problem or is critical for any particular purpose, and since an object of the Lemelson device is to inject select quantities of medications and drugs within human tissue.

#### ***Allowable Subject Matter***

Claims 35 and 36 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 1-9 and 13-31 would be allowable if rewritten or amended to overcome the rejection under 35 U.S.C. 112.

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Claims 43 and 46-51 would be allowable if rewritten to overcome the rejection under 35 U.S.C. 112 and to include all of the limitations of the base claim and any intervening claims.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Corrine McDermott (formerly Maglione), whose telephone number is (703) 308-2111. The examiner can normally be reached on Monday through Thursday from 6:30 AM to 4:00 PM. The examiner can also be reached on alternate Fridays.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0858. The fax phone number for this group is (703) 305-3590.

CMM  
July 25, 1995

*Corrine McDermott*  
*Corrine McDermott*  
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